SYLVIA SHIH-YAU WU (CSB No. 273549)
GEORGE A. KIMBRELL (*Pro Hac Vice*)
AMY VAN SAUN (*Pro Hac Vice*)
Center for Food Safety
303 Sacramento Street, 2nd Floor,
San Francisco, CA 94111
T: (415) 826-2770 / F: (415) 826-0507
Emails: gkimbrell@centerforfoodsafety.org
avansaun@centerforfoodsafety.org

STEPHEN D. MASHUDA (*Pro Hac Vice*)
Earthjustice
705 Second Avenue, Suite 203, Seattle, WA 98104
T: (206) 343-7340 / F: (206) 343-1526
Email: smashuda@earthjustice.org

BRETTNY HARDY (CSB No. 316231)
Earthjustice
50 California Street, Suite 500, San Francisco, CA 94111
T: (415) 217-2142
Email: bhardy@earthjustice.org

Counsel for Plaintiffs

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*, *Plaintiffs,* v. STEPHEN HAHN, *et al.*, *Defendants,* and AQUABOUNTY TECHNOLOGIES, INC. *Intervenor-Defendant.*	Case No. 3:16-cv-01574-VC **PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT** Date: May 13, 2020 Time: 10:00 a.m. Location: Courtroom 4 Judge: Hon. Vince Chhabria

NOTICE OF MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that the following Motion for Summary Judgment on the remaining claims in this case will be heard by the Honorable Vince Chhabria of the United States District Court for the Northern District of California on May 13, 2020, at 10:00 a.m. in Courtroom 4, on the 17th floor of the Philip E. Burton Courthouse and Federal Building, 450 Golden Gate Avenue, San Francisco, California, or as soon thereafter as counsel can be heard.

REQUESTED RELIEF

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiffs Institute for Fisheries Resources (IFR), Pacific Coast Federation of Fishermen's Associations (PCFFA), Golden Gate Salmon Association (GGSA), Kennebec Reborn, Friends Of Merrymeeting Bay, Cascadia Wildlands (Cascadia), Center for Biological Diversity (the Center), Ecology Action Centre (EAC), Friends of the Earth (FoE), Food and Water Watch (FWW), Quinault Indian Nation, and Center For Food Safety (CFS) (Plaintiffs), move for summary judgment on Claims 2, 3, 4, 5, 6, 7, 10, & 12 raised in their Amended Complaint for Declaratory and Equitable Relief, on the grounds that the FDA's approval violated the Administrative Procedures Act, the National Environmental Policy Act, the Endangered Species Act, and the Federal Food, Drug, and Cosmetic Act. This motion is based upon the pleadings and administrative record on file in this case, the points and authorities herein, and the declarations submitted herewith.

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INTRODUCTION AND SUMMARY OF ARGUMENT

Defendant FDA's assessment of Intervenor AquaBounty's genetically engineered (GE) salmon is more telling for what it does not do than what it does. Despite the GE salmon being the first commercial GE animal approval in history, FDA refused to prepare an Environmental Impact Statement (EIS), the level of National Environmental Policy Act (NEPA) compliance often undertaken for far more mundane agency actions, like timber sales or highways. When determining whether an EIS is required, courts look to the precedential nature of a decision, and one would be hard pressed to find a more unprecedented approval than presented here. Even in its Environmental Assessment (EA), FDA constrained its review to just AquaBounty's initial two facilities, sticking its head in the sand as to the company's widely broadcast plans to expand its production once it cracked open the regulatory door. And even as to those two facilities, FDA violated core tenets of law and science by betting everything on AquaBounty's containment measures, failing to analyze what would happen to endangered wild salmon if they were breached.

It is the same story for the Endangered Species Act (ESA), where FDA went to extraordinary lengths to avoid ESA Section 7 consultation. Yet the "may affect" threshold triggering consultation is exceedingly low—any possible effect—and was easily met here. Expert fisheries scientists in its sister federal agencies told FDA as much. FDA ignored these concerns and the best available science and, like it did with NEPA, instead constrained its analysis only the facilities in Canada and Panama. The ESA's policy of institutionalized caution regularly sweeps into the consultation process far less biologically consequential actions, like the installation of an irrigation pipe or issuance of a grazing permit. FDA's refusal to subject a novel, engineered form of Atlantic salmon, to be grown on the Atlantic coast near critically endangered wild Atlantic salmon, to the scrutiny of the wildlife agencies through the consultation process violates the ESA.

Finally, the Court requested further briefing on Claim 12, the environmental safety claim. FDA wants it both ways: it asks the Court to sign off on the agency's review, while also disavowing any such authority to consider the environment under the federal Food, Drug, and Cosmetic Act (FFDCA). FDA's view is wrong, and has dangerous consequences: leaving the environment

completely unprotected from GE animals, and transforming its NEPA analyses into meaningless paperwork exercises. Both FFDCA and NEPA show FDA's safety review is capacious enough to cover environmental safety; FDA acted arbitrarily by failing to adequately assure the environmental safety of GE salmon. Accordingly, the Court should grant Plaintiffs' motion for summary judgment and vacate the GE salmon approval.

FACTUAL BACKGROUND

I. THE GE SALMON APPROVAL.

FDA's approval of AquaBounty's GE salmon is the first time anywhere in the world a government has authorized the commercial production of a GE animal or fish to be sold as food. ECF 53 at ¶ 4 (App. 65, 66). In the 1990s, AquaBounty began discussions with FDA about its novel GE salmon. FDA-000001, FDA-000185. ECF 196 at 2-3. In 2008, FDA developed Guidance 187, formally announcing that the agency would extend its jurisdiction under the FFDCA to regulate GE animals as new animal drugs, interpreting the FFDCA's "safety and effectiveness" requirement to include an evaluation of environmental risks. FDA-G187-00617–19. The record shows that FDA subsequently considered environmental safety to be a key part of its FFDCA review of the GE salmon, and implemented mitigation measures intended to reduce those risks. ECF 198 at 17-19; ECF 210-3 at 12-14; FDA-022337.

In 2015, FDA approved AquaBounty's new animal drug application to produce and sell its GE salmon. 80 Fed. Reg. 73,104 (Nov. 24, 2015). FDA prepared an EA under the NEPA, but not a comprehensive EIS, ignoring serious concerns from experts, stakeholders, and Congress. *See, e.g.*, F1-00047500 (FWS Regional 5 comments); F1-00212818; F1-00047558; F1-00167784 (Drs. Kapuscinski and Sundström comments); FDA-2011CP-001 (Plaintiffs' legal petition requesting EIS); FDA-2011CP-140 (FDA's denial); F1-00002326 (Congressional letter); F1-00006910 (comments from Plaintiffs).

II. FDA'S INCOMPLETE ANALYSIS OF ENVIRONMENTAL IMPACTS.

In its EA and Finding of No Significant Impact (FONSI), FDA asserted that GE salmon pose no environmental or ecological risks because the AquaBounty's production processes at the

Prince Edward Island (PEI) and Panama sites would be subject to physical, biological, and geographic containment measures to prevent GE salmon from escape into the wild. FDA-022313-513; FDA-022514-520. Accordingly, it refused to prepare a full EIS analyzing those risks.

Among many others, preeminent scientific experts on GE fish, Dr. Anne Kapuscinski and Dr. Frederick Sundström, warned of the numerous fundamental deficiencies in FDA's data, assessment, and conclusions. F1-00212818; F1-00047558; F1-00167784. In particular, these scientists explained that FDA had made a fundamental error that permeated its review, by focusing on the containment measures (risk of exposure), and refusing to assess the impacts to the environments and wild salmon (hazard) if those GE fish nevertheless escaped. They told FDA its review had "major scientific inadequacies" and "set an unacceptably low bar," was "too narrow and its methods inadequate," F1-00167784, that the agency utilized an "outdated list of issues" and "ignore[d] the major advances in methodologies for assessing environmental risks from transgenic fish." F1-00167788; F1-00047559; F1-00212819.[1] Dr. Kapuscinski, who wrote the leading book on transgenic fish risk assessment,[2] said FDA's work was so bad that if they were a student of hers, she would have failed them. FDA-025407.

> As Drs. Kapuscinski and Sundström summarized in comments on the draft EA:
>
> > [The EA] *focuses on completing only the 'exposure' step of risk assessment,* and concludes there is 'extremely small' likelihood of exposure due to multiple confinement at the two facilities, thus no consequences and no need to assess consequences. As scientists, we cannot agree with this approach because it assumes 100% achievement of multiple confinement without having presented the failure mode analysis that is standard practice in technology risk assessment. Even if actual exposure is very close to zero, *it is still necessary to assess ecological consequences, from low to high severity consequences, and then estimate overall risk.*

F1-00047561 (emphases added); F1-00213328. Dr. Kapuscinski further explained in a 2013 interview that FDA's approach was contrary to Risk Assessment 101:

> Risk assessment normally has three steps. One, you identify what the hazard is. Two, you figure out what the consequences would be to the environment if the hazard were to be realized. And the third step is, you say 'well, can we somehow manage the

[1] Given space constraints, Plaintiffs do not quote other important aspects of Drs. Kapuscinkski and Sundström's criticisms. The experts' full comments will be included in the Joint Appendix. *See also* F1-00213326, F1-00213331 (Plaintiffs' comments on EA); ECF 53 at ¶¶ 97, 109-10 (Compl.).
[2] Kapuscinski, A., et. al., ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS, VOLUME 3: METHODOLOGIES FOR TRANSGENIC FISH, CABI (2007).

> risk, can we do something to prevent the consequences from happening?'
>
> What FDA has done, in both the 2010 draft and 2012 draft EA, is *essentially skip to step three*. … They are *still hanging their whole conclusion on risk management* – that is, multiple confinement systems for the fish.
> …
> A key part of step two is a consequence assessment. That's where one is asking, '*if the fish did escape, what would happen, could that harm the environment*?'

F1-00213329-30 (quoting FDA-025403) (emphases added).

Despite relying on the indefinite, 100% efficacy of confinement to avoid GE salmon harms, FDA failed to substantiate the reliability of the PEI containment measures by undertaking an actual quantitative "failure mode analysis," the standard for technology assessment. F1-00167784; F1-00167788-90; F1-00047500-501. Physical confinement measures are "especially prone to equipment failures, power failures, operational wear, and human error," F1-00167789. AquaBounty admitted at least one such weather event has already occurred. F1-00003483; F1-00062532. In another incident, despite claimed air-tight confinement, a dangerous salmon virus entered the facility, requiring AquaBounty to kill many of its fish. The company never figured out how the virus entered. F1-00004200.

However, the breakdown of AquaBounty's containment measures and the accidental release of the novel GE fish into the natural environment pose significant environmental risks. For example, as Dr. Johnathan Rosenfield, an expert fish biologist, told FDA: GE salmon are "likely to escape captivity" and when they do, will likely "wreak havoc on natural ecosystems, endangered species, and/or commercially valuable fisheries." FDA-029456. Dr. Rosenfield detailed how GE salmon may escape, given the hydrological connection between the PEI facility and the environment, and the flaws in FDA's assumptions about perfectly trained employees and its failure to consider avenues of escape other than vandalism or physical disaster. FDA-029457-60; *see also* FDA-022348 (FDA acknowledging small life stages of fish can be difficult to contain, impossible to re-capture); FDA-022376 (PEI facility is "close to the Fortune River" and a "coastal estuary" connected to the Atlantic). Indeed, even FDA's EA acknowledged the many potential routes of escape from the PEI facility. FDA-022379-80; FDA-022398-99; *see also* F1-00168338 (more scientists commenting on escape risks).

Scientists also explained to FDA that, however low FDA judged the risk of accidental release, the corresponding impacts if it occurred were potentially catastrophic. Experts explained that, despite the claimed "geographic" confinement, GE salmon are in fact quite capable of surviving outside the PEI facility, where they may cause lasting impacts to the native salmon population. FDA-029460-66; FDA-022401, FDA-022423 (FDA recognized that salmonids found on PEI, with which GE salmon could spawn). These numerous significant and irreversible impacts of GE salmon release include ecological impacts, through predation or competition for resources or mating, or genetic impacts, via hybridization and genetic introgression. FDA-029467-69. Past studies of escaped farmed fish show they "may jeopardize wild populations," and genetic impacts can arise even if fish are not fertile, through competition and false mates, especially with fish engineered to grow faster than normal. FDA-022359, FDA-022434 (growth is faster); FDA-022363 (other behaviors affected by genetic engineering may make GE salmon "more competitive"). Even more worrisome, successful reproduction with wild salmon is a "clear danger, the consequences of which would likely be irreversible" and "uniquely troubling" because of the novelty of the GE salmon genetics. FDA-029469-78. Nor are all GE salmon sterile: the PEI facility houses fertile broodstock, and sterility of grow-out fish is ranges from 95%-99%, meaning at current capacity PEI could be producing as many as *half-a-million fertile eggs*,[3] regardless the "biological" confinement. While acknowledging fertile GE salmon escaping the PEI facilities was the "greatest potential risk" to the environment, FDA-022432-5, FDA never fully analyzed those impacts and dismissed the need to do so with conclusory statements that escape was "highly unlikely" or had "very low" likelihood. *See, e.g.*, FDA-022419, FDA-022436.

The experts warned FDA also made other fundamental errors and did not account for scientific uncertainty, including:

- Failing to provide important underlying data for its conclusions including sample sizes,

[3] Currently, AquaBounty's PEI facilities can hold up to 13,000 fish with the capacity to produce as many as 10 million GE salmon eggs per year. Environmental Impact Statement, Proposed Acquisition of Snow Island's Atlantic Sea Smolt Ltd. Facility, at 17-18, Report Prepared for Aqua Bounty Canada Inc., May 19, 2016, http://www.gov.pe.ca/photos/original/CLE_2016_AquaBo.pdf. FDA's EA stated that the criteria for shipping eggs would be showing 95% triploidy (with a probability of less than 0.05 that the percentage of sterile fish is any lower), FDA-022374-76; if 5% of 10 million eggs are fertile, that equals half a million eggs.

standard errors, statistical power, and statistical tests used to reach its conclusions, F1-00047561;

- Failing to consider newer research on transgenic fish risks, showing "high scientific uncertainty in predicting their overall fitness and ecological effects." Thus FDA's conclusions "could be very misleading" and were "overly simplistic." F1-00047561-62. Instead FDA focused on "outdated risk assessment ideas." F1-00167785;
- Failing to undertake a scientific "uncertainty analysis," another key part of basic environmental risk analysis, to identify and treat uncertainties throughout the exposure and consequence assessment. F1-00047562; F1-00167792; and
- Violating a "fundamental ecological principle" by using the wrong comparator (farmed salmon instead of wild salmon) in assessing environmental effects. F1-00047564.

Drs. Kapuscinski, Sundström, and Rosenfield were far from alone in their critiques of FDA's lack of data, the uncertainty, and the need for a more comprehensive review of all potential harms from GE salmon. Dr. Hallerman, one of FDA's presenters at its Veterinary Medicine Advisory Committee (VMAC) meeting, stated that the "development of quantitative risk assessment is presently incomplete … especially regarding the likelihood of harm given exposure to the hazard. We need more studies quantifying net fitness, especially under near-wild, or wild, conditions." FDA-015361; FDA-015355 ("we have a lot to learn about the likelihood of genetic harm being realized due to the interbreeding of wild and transgenic aquacultured fish."). Even members of FDA's VMAC realized the flaws and gaps in FDA's environmental analysis. Dr. Thorgaard—the only fish scientist on the VMAC panel—concluded that in light of these concerns, "considering this issue in a comprehensive way, together with other agencies through an environmental impact statement, would be the best way to proceed." FDA-015658; *see also* F1-00062522-41 (Food and Drug Law Institute critique); F1-00168345 ("A robust and formal risk assessment is warranted"); F1-00179858. Indeed, the very same leading scientists whose studies FDA relied on in its EA confirmed the high degree of scientific uncertainty. *See, e.g.*, FDA-022350, FDA-022361, FDA-022363-64, FDA-022375-76, FDA-022421, FDA-022429, FDA-022434, FDA-022452-53, FDA-022457, FDA-022452-61 (Final EA relying on and citing older studies by Drs. Kapuscinski, Hallerman, Devlin, NRC, etc.); F1-00213359-60, F1-00213369-70 (comments to FDA citing Devlin and NRC studies); FDA-029489-501 (NRC research gaps memo and excerpt of

report). Government scientists in the expert wildlife agencies also expressed alarm over significant endangered wild salmon risks. *See* F1-00047500 (FWS comments) and *infra*.

III. FDA'S NARROW ANALYSIS OF THE SCOPE AND EFFECTS OF ITS APPROVAL.

Throughout the process, AquaBounty made no secret that its business plan was far broader than the two initial experimental facilities. Limiting the scope was a way to limit public controversy and to break through the regulatory door. But the company's business plan has always been to dramatically expand production, including: 1) expanding its facilities on PEI; 2) buying or building new facilities in other locations in U.S. and worldwide; and 3) selling eggs to third parties to grow. Time has proven this not just foreseeable, but fact.[4] AquaBounty's commercial production already looks far different than the scale and means FDA approved.[5]

Numerous record documents, including AquaBounty's statements to FDA and other regulators, show that FDA knew of AquaBounty's expansion plans. FDA-015389 (AquaBounty CEO testifying to FDA in 2010 their intent to increase production: "The kinds of facilities that we are thinking will be constructed in the United States and other locations are perhaps on the order of 2,000 tons"); FDA-2011CP-013–015 (informing FDA in 2011 of AquaBounty's expansion plans). For example, in its 2014 Form 10 to the Securities and Exchange Commission, AquaBounty stated "we currently plan to increase our supply of unfertilized Atlantic salmon eggs through either expansion of our existing Canadian hatchery or through the purchase of an existing egg producer." F1-00175757 ("we currently plan to apply for regulatory approval of a second hatchery that would likely be located in the United States."). The record also includes multiple

[4] In just the time this case has been pending, AquaBounty has greatly expanded its PEI facilities, closed its Panama facility, ECF 201, and opened a new facility in Indiana. CBC News, *Expansion of GMO salmon facility approved by province: Any escapes from AquaBounty hatchery in Rollo Bay West must be reported to the government* (June 23, 2017), https://www.cbc.ca/news/canada/prince-edward-island/pei-AquaBounty-gmo-rollo-bay-west-1.4174761; Undercurrent News, *AquaBounty inks $14m deal for US site to grow GM salmon on land* (June 13, 2017), https://www.undercurrentnews.com/2017/06/13/AquaBounty-inks-14m-deal-for-us-site-to-grow-gm-salmon-on-land/.

[5] The Fish Site, *AquaBounty Unveils 50,000 tonne target* (Jan. 17, 2020), https://thefishsite.com/articles/aquabounty-unveils-50-000-tonne-target (reporting AquaBounty's near-term plan to construct four to five new facilities in North America, that they are seeking regulatory approval in Brazil, Argentina, Israel, and China, and once approved will commercialize with partners, joint ventures, and licensing, i.e., other people growing their eggs).

requests from third parties to buy AquaBounty's GE salmon eggs, and grow them at other facilities. F1-00213343 (citing FDA-2011CP-109-111 and FDA-021204); F1-00213344; F1-00006900. While FDA knew of these expansion plans throughout the process, and despite numerous expert scientists highlighting the need to consider AquaBounty's expansion plans to conduct a sound risk assessment, FDA refused to address the risks from expansion in its approval. F1-00047500; F1-00167786-88; FDA-029478.

Finally, salmon are an important commercial and recreational fishery for many communities and in many native societies have a uniquely important cultural place. F1-00065383; F1-00219654; F1-00220001; F1-00240905; F1-00179757; ECF 198-4 (James Decl.). Despite many commenters raising concerns of downstream economic, social, and cumulative impacts to wild salmon fisheries should GE salmon escape, especially from expanded operations, *e.g.*, F1-00267341, FDA refused to consider at all these potential impacts. FDA-022329; FDA-022332; FDA-022441 (EA has only one paragraph on the potential impacts to salmon in Maine).

IV. FDA'S INCOMPLETE ANALYSIS OF ENDANGERED WILD ATLANTIC SALMON.

The Gulf of Maine Distinct Population Segment of Atlantic salmon is protected as endangered under the ESA. *See* 74 Fed. Reg. 29,344 (June 19, 2009). This is the last wild population of Atlantic salmon in the United States and, because it numbers less than 1,000 fish, is the focus of intensive recovery efforts.[6] The National Marine Fisheries Service (NMFS) has recognized that aquaculture poses both ecological and genetic risks to Atlantic salmon. 74 Fed. Reg. at 29,372-29,273. As early as 2001, both the U.S. Fish and Wildlife Service (FWS) and NMFS (the Services) urged FDA to undergo ESA Section 7 consultation if it was considering approving AquaBounty's plan to grow and sell GE salmon, citing its "potential to adversely affect endangered wild salmon." FDA-001096. FDA initially agreed consultation was necessary: that the probability of escape and uncertainty that is acceptable "*must be determined through consultation* and agreement with the appropriate agencies, e.g., NMFS." FDA-001382 (emphasis added), and in 2009,

[6] *See* NOAA Fisheries, Atlantic Salmon-Protected, https://www.fisheries.noaa.gov/species/atlantic-salmon-protected (NMFS status summary).

requested consultation. *See, e.g.*, FDA-008858; Mashuda Decl. Exhibits 1-2.[7] NMFS responded, concluding that "the [GE salmon] proposal *may have effects* on endangered species." FDA-008890 (emphasis added). In 2010, FDA concluded that its approval "may affect" but was "not likely to adversely affect" endangered Atlantic salmon. ECF 66 at 2.

After reviewing FDA's EA, many FWS regional offices expressed major concerns, which mirrored those from outside scientists, about FDA's analysis of the risks and consequences of GE salmon escape. *See, e.g.*, FDA-015798-803; Ex. 11, at 8-9 (2013 Memo for Director); Ex. 12 (Region 5 comments); Ex. 6 at 1 (summary of regional and headquarters staff comments and concerns noting that "Additional, *more rigorous* biological risk assessments *should* be conducted.") (emphasis added); *id*. ("The process of pressure treating eggs to produce triploid eggs is an imperfect process."); *id*. ("[T]he information provided about the likelihood of establishment is [] not adequate"); *id*. ("[I]t is unclear how the FDA will assure, monitor, and verify that multiple confinements are continually achieved at the two facilities or future facilities."); Many FWS regions agreed that "[i]f escapement occurs of reproductively viable GMO salmon, potential for [reproduction] with wild Atlantic salmon, and disruption of the local genetic adaptations and traits of the native stock is of concern." *Id.*; *see also* Exs. 17, 19, 23. The agency also had "future concerns" about AquaBounty's plans to grow GE salmon in seawater in the future. Ex. 6 at 2. All but one FWS region *opposed* FDA approval of the GE salmon based on these concerns. Ex. 11 at 9 (March 2013 Memo to Director).

Despite these concerns, FWS later suggested FDA should clarify the approval would have "no effect" on listed salmon. FDA-015672; Ex.4. Hence, in subsequent letters, FDA stated that it now believed that approval of AquaBounty's application under the then-proposed use conditions would instead have "no effect" on endangered Atlantic salmon populations. FDA-015675; FDA-015678. FDA requested that the Services concur with this "no effect" determination. *Id*. In response, FWS reversed course from its earlier comments and "concurred" with FDA's "no effect" determination based on FDA's characterization of the limited scope of the GE salmon approval.

[7] The documents references as "Ex." in this brief refer to the Exhibits attached to the Declaration of Stephen D. Mashuda, filed herewith.

FDA-015785. FWS staff, however, continued to express concerns about the effects on endangered Atlantic salmon. Ex. 2 at 1 (Jan. 2, 2013 email "Although AquaBounty claims their fish are sterile, that sterilization process is not 100 percent. There is the possibility that some of these fish could escape and reproductively interact with native salmon" and reduce fitness of wild fish); FDA-016593 (FWS official warning that even FDA's limited view of approval warrants a no effect determination, the "narrow activity could turn out to be a foot in the door."); *see also* Ex. 9 at 3.

Unlike FWS, NMFS did not "concur" with FDA's "no effect" determination (rather, internal NMFS correspondence indicates that NMFS staff did not agree with this determination), and merely acknowledged FDA's "no effect" determination. FDA-017258. NMFS did this to avoid being "legally complicit" in FDA's decision and preferred to rest on their comments in the record expressing their concerns. Ex. 27; *see also* Ex. 21.

STANDARDS OF REVIEW

Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Challenges to final agency actions under the FFDCA, NEPA, and the ESA are reviewed under the APA standards of judicial review for agency actions, which require the Court to "hold unlawful and set aside" decisions that are, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or adopted "without observance of procedure required by law." 5 U.S.C. § 706(2). In determining whether an action is "arbitrary and capricious" the Court evaluates whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An action is arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 43. Finally, although courts typically review APA claims based

on the administrative record, courts "may consider evidence outside the administrative record for the limited purposes of reviewing" claims that arise under the ESA. *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 497 (9th Cir. 2011). *See also* ECF 66 at 5, n.1.[8]

ARGUMENT

I. FDA VIOLATED NEPA.

NEPA is "our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1215-16 (9th Cir. 1998). FDA's EA is fatally flawed because FDA failed to take the requisite "hard look" at the consequences of its decision, *Friends of the Payette v. Horseshoe Bend Hydroelectric Co.*, 988 F.2d 989, 993 (9th Cir. 1993); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971), and failed to provide a "convincing statement of reasons" in support of its FONSI. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1220 (9th Cir. 2008). FDA failed to adequately analyze impacts it acknowledged even within its own unlawfully limited scope, and completely failed to assess the broader suite of direct, indirect, interrelated, and cumulative impacts caused by its approval. A full EIS is required.

A. FDA Failed to Take a Hard Look at Impacts.

NEPA regulations require agencies to analyze (take a "hard look" at) all direct, indirect, and cumulative impacts of their actions. *Blue Mountains*, 161 F.3d at 1211; 40 C.F.R. §§ 1508.8; 1508.9; 1508.13; 1508.18; 1508.27. NEPA's core "hard look" mandate requires "considering all foreseeable direct and indirect impacts" and analyzing adverse impacts in a manner that "does not improperly minimize negative side effects." *League of Wilderness Defenders-Blue Mountains Biodiversity Project v. U.S. Forest Serv.*, 689 F.3d 1060, 1075 (9th Cir. 2012). In doing so, FDA must apply "accurate scientific" information of "high quality," and ensure the scientific integrity of its analyses. 40 C.F.R. §§ 1500.1(b), 1502.24.

[8] As demonstrated by the declarations submitted with the previous partial summary judgment motion, ECF 198-1 to 198-9, Plaintiffs have standing. *See also* ECF 225 at 15 n.15 (noting that FDA did not dispute standing to challenge the GE salmon approval).

FDA flunked these NEPA requirements. First, the record is stocked with information—including from scientific experts and other agencies—detailing the extensive direct and indirect ecological threats if and when GE salmon escape AquaBounty's confinement. *Supra* pp.4-5.[9] FDA failed to consider what will be the impacts on wild fish and ecosystems after some inevitable accident, storm, or human error, when the GE salmon are released and enter the natural marine environment. These significant—potentially catastrophic—threats include competition for food and habitat, interbreeding, and broader risks to the aquatic food chain. *Id.* Yet FDA arbitrarily failed to take a hard look at these impacts. *State Farm*, 463 U.S. at 43 (failure to consider an "important aspect of the problem" is arbitrary).

Second and relatedly, FDA failed NEPA's hard look mandate because it only looked at *part* of the risk assessment equation, leaving the above risks unaddressed. Sound risk assessment requires data and analysis of both (1) exposure, here the risk of inadequate containment measures, but also (2) hazard, here, *what will happen if the GE salmon nonetheless are released into the environment*. The agency vitiated core legal and scientific standards by putting all its (fish) eggs solely in the "containment" basket. Because FDA concluded the production facilities would be subject to physical, biological, and geographic containment measures that it believed made the risk of escape "low," it decided its job was done. That decision was contrary to law, science, and common sense.

Experts repeatedly explained to FDA that this limited scope and lack of data were contrary to well-established principles of risk assessment, which require analysis of not just the containment measures, but also (and commonsensically) what happens if they fail. *Supra* pp.2-4.
Rather than follow that path, FDA instead (recognizing Dr. Kapuscinski's singular expertise) attempted to support its approach by repeatedly citing to Dr. Kapuscinski's work in the early 1990s, despite Dr. Kapuscinski's direct warning that it had long been "replaced by better methods." FDA-025406; F1-00213330. Kapuscinski said that FDA's citation of her work in this way was so dishonest that if a student did it, "we would fail them. Students would get into serious trouble if they were citing really old methods, and there had been huge advances in the methods since then and they ignored that. That would be a reason to fail them." FDA-025407. It also fails

[9] For example, *see* detailed comments of Dr. Johnathan Rosenfield. FDA-029456.

NEPA. 40 C.F.R. §§ 1500.1(b), 1502.24.

FDA's failings were not just contrary to core scientific standards, but also well-established NEPA caselaw. *Alaska Wilderness League v. Kempthorne*, 548 F.3d 815, 832 (9th Cir. 2008) ("An agency should assess the likelihood of a particular risk along with the consequences of such an accident") (citing *City of New York v. U.S. Dep't of Transp.*, 715 F.2d 732, 746 (2nd Cir. 1983) ("It is only the risk of accident that might render the proposed action environmentally significant. That circumstance obliges the agency to undertake risk assessment: an estimate of both the consequences that might occur and the probability of their occurrence")); *New York v. Nuclear Regulatory Comm'n*, 681 F.3d 471, 482 (D.C. Cir. 2012) ("[A]n agency conducting an EA generally must examine both the probability of a given harm occurring and the consequences of that harm if it does occur").

Third, despite letting everything sink or float on the 100% efficacy of the AquaBounty containment measures, FDA also failed to conduct a risk assessment standard "failure mode analysis" of those measures, needed to "substantiate their reliability." F1-00167784, F1-00167788-89. For example, as experts pointed out, FDA relied on the "biological confinement" of sterility, but admitted that up to 5% of the GE salmon might *not* be sterile, which could amount to *half a million* fertile fish eggs produced annually at PEI, based on AquaBounty's current production scale estimates. *Supra* n.3. And of course, the broodstock in the PEI facility is not sterile. Similarly, experts questioned physical confinement measures without any failure mode analysis, especially with evidence of least one weather event and one instance of a salmon virus breaching these containment measures. *Supra* pp.3-4. And contrary to FDA's claims of geographic confinement, the waters around the PEI facility can and do support salmon populations, and GE salmon could also survive and thrive there. *Id.* Without a quantitative failure mode analysis, FDA can offer no assurances that the various AquaBounty containment measures are sufficient to eliminate the threat of release or escape and the potential significant environmental effects associated with it.

Even if FDA *had* tried to substantiate its dismissal of escape risks as remote, NEPA does not give it a free pass from analyzing those risks, particularly given the potentially catastrophic danger it would create. *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Com'n*, 449 F.3d 1016,

1028-33 (9th Cir. 2006) (EA's failure to consider environmental effects of a terrorist attack on nuclear facility because attack was "remote and highly speculative" was arbitrary and capricious, and contradicted by the government's efforts to combat the same) (citing and quoting 40 C.F.R. § 1502.22 (b)(4)) ("'reasonably foreseeable' includes impacts which have catastrophic consequences, even if their probability of occurrence is low…").

Fourth, the experts also warned that FDA's analysis lacked basic data for numerous issues, and failed to undertake a formal uncertainty analysis, despite dealing a new GE animal that carries novel risks. *Supra* pp.5-6. Numerous other scientists, including those presenting at FDA's public meeting, as well as scientists from the expert wildlife agencies, criticized FDA's assessment and warned of dangers. *Supra* pp.6-7. In sum, scientists warned that FDA must utilize additional, more comprehensive studies, and up-to-date scientific methods to assess risks. Experts emphasized that the unique and extremely uncertain kind and extent of harm escaped or released GE salmon may cause to ecosystems. FDA nonetheless failed to take a hard look at these potential effects. 40 C.F.R. §§ 1500.1(b), 1502.24.

Fifth, there is also record evidence of significant downstream risks to commercial wild fisheries and communities that depend on them from accidental release of a novel GE fish. *See supra* pp.4-5, 8. Contamination of wild populations by GE salmon could have devastating impacts on salmon fisheries and markets. *Id.* Additionally, there could be irreparable damage to biodiversity and native and cultural traditions that depend on salmon, which hold a sacred place in many cultures. *Id.* FDA nonetheless refused to analyze these potential impacts, claiming that as a matter of law it is only required to consider those types of potential impacts if it *first* concludes that an EIS is required solely based on environmental impacts. FDA-022517 ("social and economic effects must be considered only once it is determined that the proposed agency action significantly affects the physical environment."); FDA-022329.

That was plain error: While economic or social effects cannot in *isolation* require an EIS, it violates NEPA to ignore them when, as here, they are *interrelated* with environmental effects. 40 C.F.R. §§ 1508.14, 1508.8. Indeed, courts have held the same risk of transmission of genetically engineered DNA from GE crops to conventional crops requires an EIS for similar reasons,

including interrelated economic effects on farmers. *Ctr. for Food Safety v. Vilsack*, 2009 WL 3047227, at *7-8 (N.D. Cal. Sept. 21, 2009) (ordering an EIS for failure to analyze these effects); *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *7 (N.D. Cal Feb. 13, 2007) (same). These courts did not hold that socioeconomic impacts had to be considered only because an EIS was already required. Rather, they considered the intertwined socioeconomic effects of GE contamination as part of the initial EIS significance threshold question. *Id.* The same is true here.

B. An EIS is Required Because GE Salmon May Have Significant Impacts.

Without the requisite "hard look" at all impacts, FDA ignored the significance of its decision and failed to undertake a rigorous EIS instead of an EA. Where "substantial questions are raised as to whether a project … *may* cause significant degradation of some human environmental factor," an agency must prepare an EIS. *Ctr. for Biological Diversity*, 538 F.3d at 1219-20 (emphasis in original). Plaintiffs "need not show that significant effects *will in fact occur*," but only that there are substantial questions, *id.*, to meet this "low standard." *Klamath Siskiyou Wildlands Ctr. v. Boody*, 468 F.3d 549, 562 (9th Cir. 2006). As shown above, this low standard was met; very substantial questions were raised, which should have mandated a full EIS.

FDA failed to address these substantial questions, and completely failed to assess the significance factors in the NEPA regulations. Whether an action may be significant and trigger an EIS requires consideration of the NEPA "context" and "intensity" factors. 40 C.F.R. § 1508.27; 21 C.F.R. § 25.42(b). These factors include, as applicable here, the degree to which the effects are likely to be highly controversial (factor 4); the degree to which effects are highly uncertain or involve unique or unknown risks (factor 5); whether the action establishes a precedent for future actions or represents a decision in principle about a future consideration (factor 6); the degree to which the action may affect endangered or threatened species (factor 9); the degree to which the action may cause loss or destruction of significant scientific, cultural, or historical resources (factor 8); and whether the action is related to actions with individually insignificant but cumulatively significant impacts (factor 7). *Id.* While only one factor is sufficient to trigger an EIS, *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 864-65 (9th Cir. 2005), here all of these factors are present.

1. FDA's Approval of First GE Animal for Human Consumption Meets the Intensity Factors.

Rather than complete an EIS, FDA issued a FONSI based on the erroneous assumption that GE salmon would never escape. *Supra*. But the record shows that escape is possible and the associated risks are great, ranging from ecological disruption to species extinction. *Supra*, *see, e.g.* FDA-029457-78. At a minimum, FDA must recognize that the possible environmental consequences are highly controversial and uncertain, and particularly threatening to this fish's only remaining wild counterpart in the U.S., the endangered Atlantic salmon.

Although FDA failed to engage in the analysis, several intensity factors tip heavily in favor of an EIS. First, the approval could not be more "precedent-setting" (factor 6), for both GE animals/fish in general and for GE salmon. This is the *first time in history* any country has approved the commercial production of a GE animal, and the GE animal happens to be one that migrates thousands of miles through the ocean. *Supra*. Not only is this technology new, FDA's oversight of GE animals as "animal drugs" is a brand-new program (for which the agency did not prepare an EIS either). This NEPA assessment will set the standard for all future GE animals, including data and scientific rigor. It will also set the precedent for future "AquAdvantage" GE salmon, as can be seen with Indiana facility.[10] Avoiding the "thoughtless setting in motion of a 'chain of bureaucratic commitment that will become progressively harder to undo the longer it continues'" is exactly why agencies must assess the precedential nature of actions when determining whether to complete an EIS. *Presidio Golf Club v. Nat'l Park Serv.*, 155 F.3d 1153, 1162-63 (9th Cir. 1998).

Second, the GE salmon is highly controversial (factor 4) meaning there is "a substantial dispute [about] the size, nature, or effect of the major Federal action rather than the existence of opposition to a use." *Ctr. for Biological Diversity*, 538 F.3d at 1222 (internal citation omitted) (holding plaintiffs satisfied the "controversy" factor of significance because the effect of fuel standards was center of controversy). The effects of this approval are controversial, given the

[10] That EA "relies extensively on the previous EA prepared by FDA for the AquAdvantage Salmon NADA approved in November, 2015,"challenged here. FDA, Environmental Assessment Supplement to NADA 141-454 to allow the grow-out of AquAdvantage Salmon at AquaBounty Technologies, Inc.'s Indiana Facility, 1 (April 20, 2018) https://www.fda.gov/media/112655/download.

scientific dispute about the potential for GE salmon to escape confinement and the resulting adverse impacts to the environment. *Supra* pp.4-5, 6. Controversy also surrounds the size/scope of FDA's review, with experts warning that FDA's approval would proliferate sales of GE salmon eggs for grow-out in facilities beyond just the initial Panama site and calling on the agency to take a broader look. F1-00167786; FDA-029456, *supra* pp.7-8.

Third, the risks of a new GE organism to marine ecosystems are uncertain, unique, and unknown (factor 5). The deficiencies in the science underlying FDA's FONSI show the need for comprehensive EIS that uses science-driven risk assessment following best standards. *Supra* pp.3-6. The high degree of uncertainty here was confirmed by leading scientists, whose studies were cited and (mis)-relied on in FDA's EA. *Supra* p.6. Uncertainty is not a reason to throw up hands and allow the proliferation of a novel GE fish and potentially irreversible consequences of its release into the environment; it is a reason for full study in an EIS. An agency's "lack of knowledge does not excuse the preparation of an EIS; rather it requires the [the agency] to do the necessary work to obtain it." *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 733 (9th Cir. 2001). An approval may have significant impacts where it effects are uncertain, and where an EA lacks certainty on one or more issues, is the agency's job to provide "justification regarding why more definitive information could not be provided." *Blue Mountains*, 161 F.3d at 1213.

Fourth and finally, the cumulative impact of adding a further threat to the already-imperiled wildlife that could be impacted by GE salmon (factor 7), *see infra*, including species protected under the ESA (factor 9), *infra* pp. 24-30, that are significant cultural resources (factor 8), *supra* p.8, lays bare the necessity of a full and thorough review. 40 C.F.R. §§ 1508.7, 1508.27(b)(7), (b)(8), (b)(9). FDA must look before it leaps into the brave new world of GE animals, and the intensity factors and substantial questions satisfy the "low standard" for an EIS.

2. FDA Cannot Mitigate its Way Out of Significant Impact.

FDA also unlawfully relied on AquaBounty's containment measures, a form of mitigation, to reach a "mitigated FONSI" and avoid preparing an EIS. 40 C.F.R. §§ 1502.14(f), 1502.16(h). Courts scrutinize mitigation measures to see whether they actually keep impacts below the "low" EIS threshold. *Klamath Siskiyou Wildlands Ctr.*, 468 F.3d at 562. FDA cannot rely on the mitigation

as a substitute for fulfilling its obligation to actually analyze potential impacts. *N. Plains Res. Council v. Surface Transp. Bd.*, 668 F.3d 1067, 1085-86 (9th Cir. 2011). But it did exactly that, failing to analyze what ecological havoc the GE salmon might wreak if/when they enter the environment or conduct a quantitative failure mode analysis to test the reliability of the containment measures, among other things. *See supra* pp.4-5. As commenters pointed out, FDA also failed to explain how it will monitor continued compliance with the containment measures at PEI or any future production facility, given AquaBounty's plans to expand production to various sites around the world. *E.g.*, F1-00167787; FDA-029458, F1-00047500. Nor did FDA consider or analyze any *alternative* mitigation measures, *see infra* (Alternatives argument). Finally, FDA disavows authority over the mitigation, despite the legal requirement that FDA have authority and control over those measures in order to rely on them in a mitigated FONSI.[11]

C. FDA Violated NEPA by Applying an Unlawfully Narrow Scope.

While as explained above FDA's NEPA assessment violated the statute's mandates even *within* the scope the agency chose to assess, FDA also violated NEPA by sticking its head in the sand, and not looking *beyond* that narrow scope. Ignoring AquaBounty's expansion plans, FDA segmented its review to just the two facilities, failing entirely to consider the full impacts of approving GE salmon, and what incremental impact the threat of GE salmon might have on already-imperiled wild salmon. It further cabined its review with an extremely limited purpose that foreclosed consideration of reasonable alternatives, the "heart" of the NEPA analysis. NEPA requires FDA to analyze in an EIS at the outset the full breadth and all reasonably foreseeable consequences of its approval.

1. Improper Segmentation

It is no accident that AquaBounty sought approval for its first-of-its kind GE fish in the manner it did: using small, experimental-size facilities, located on foreign grounds in Canada and

[11] Council on Envtl. Quality, *Final Guidance for Federal Departments and Agencies on the Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact*, 76 Fed. Reg. 3843, 3844 (Jan. 21, 2011) ("It is an agency's *underlying authority* that provides the basis for the agency to commit to perform or require the performance of particular mitigation") (emphasis added).

Panama, and preposterous transportation scheme to airlift fish eggs over the United States and ship them back in a manner that it knew would never be commercially viable. Rather, this strategy was intended to pry open the U.S. regulatory door, but at the same time keep the review of the risks of this unprecedented action as narrow as possible. Yet since the beginning of the regulatory process, the company has been engaged in efforts to further expand the production of GE salmon to (1) expand and establish other production facilities in the U.S. and around the world, and (2) to sell its eggs to other facilities. AquaBounty made no secret of its plans to its investors or to regulators. *Supra* pp.7-8.

Although the risk assessment is already outdated and no longer represents the reality of AquaBounty's GE salmon operations, FDA may claim there is nothing to worry about, because FDA can assess AquaBounty's next steps piecemeal, avoiding any comprehensive evaluation of the entire operation and the full consequences of approving GE salmon. But that misses the forest for the trees, violating NEPA's mandates. NEPA prohibits an agency from doing exactly what FDA did here: dividing a project into multiple actions, or "breaking it down into small component parts," in order to avoid a determination that "the action is related to other actions with individually insignificant but cumulatively significant impacts." 40 C.F.R. § 1508.27(b)(7) ("Significance cannot be avoided by … breaking [an action] down into small component parts."). Rather, when determining the scope of its environmental review under NEPA, an agency must consider "connected, cumulative, or similar" actions *together* to prevent an agency from "dividing a project into multiple 'actions,' each of which individually has an insignificant environmental impact, but which collectively have a substantial impact." *Earth Island Inst. v. U.S. Forest Serv.*, 351 F.3d 1291, 1305 (9th Cir. 2003); 40 C.F.R. § 1508.25. "Connected actions" include actions that are "interdependent parts of a larger action and depend on the larger action for their justification." 40 C.F.R. § 1508.25. AquaBounty's long-planned expansion completely depended on FDA's approval of its GE salmon. FDA was not required to know everything that would go on later, but it was required to analyze that which was reasonably foreseeable at the time of its approval, including AquaBounty's already-in-motion business plan. *Supra* pp.7-8.

Instead FDA impermissibly segmented its review of the effects of AquaBounty's GE salmon

by considering production only at the Panama and PEI sites, when this approval is only the first step in the company's public plans to commercially develop their GE salmon. This constrained scope of review prevented FDA from properly considering the potentially significant environmental and ecological impacts associated with known and reasonably foreseeable connected, similar, and cumulative actions to expand production of AquaBounty's GE salmon in other areas and at other sites, or sell eggs to be grown at different sites, including the U.S., Canada, Argentina, Chile, China, and other parts of the world, as previously and repeatedly announced by the company. *Supra* pp.7-8.

Even if the evidence of AquaBounty's broader business plan had not been so clear, a lack of certainty as to the precise nature of future actions in no way negates FDA's duty to consider them. "[T]he basic thrust of [an agency's responsibilities under] NEPA is to predict the environmental effects of proposed action before the action is taken and those effects fully known. Reasonable forecasting and speculation is thus implicit in NEPA and we must reject any attempt by agencies to shirk their responsibilities under NEPA by labeling any and all discussion of future environmental effects a 'crystal ball inquiry.'" *Save our Ecosystems v. Clark*, 747 F.2d 1240, 1246 n.9 (9th Cir. 1984) (quoting *Scientists' Instit. For Public Info. v. Atomic Energy Comm'n*, 481 F.2d 1079, 1092 (D.C. Cir. 1978)); *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002).

FDA claims that changes to the approved process for producing AquaBounty's GE salmon, including expansions, will be subject to the agency's supplemental application process; however later piecemeal assessments of individual projects, even if they are done,[12] are no substitute for an overarching EIS at the outset. Nor does a promise to comply with separate NEPA duties later fulfill FDA's current NEPA duties for this approval. This death by a thousand cuts is exactly why NEPA's

[12] AquaBounty did prepare an isolated EA for its Indiana facility, *supra* n.10, but notably did *not* for its expansion on Prince Edward Island, which greatly expanded its operations, holding up to 13,000 fish and the capacity to produce upwards of 10 million eggs a year. *See supra* n.3. Further, the agency cannot assure future changes will be subject to additional environmental analysis and public review, even if they have the potential to cause significant impacts. 21 C.F.R. § 514.8. "Moderate" or "major" manufacturing changes require an applicant to submit a supplemental application, but the regulations leave it to the applicant to determine what qualifies. *Id.* § 514.8(b)(2), (3). "Minor" changes do not require any additional approval at all. *Id.* § 514.8(b)(4). Even for supplemental applications, it is up to FDA whether or not to require any further NEPA analysis, or rely on the original EA. FDA-G187-00601; *supra* n.10 at 1; 21 C.F.R. §§ 25.20, 25.33.

threshold for an EIS is low. FDA's segmented review means that the broader, cumulative risks and impacts of the AquaBounty approval may never be analyzed, and violates NEPA's fundamental requirement that such impacts be analyzed at the earliest possible time, before the agency makes a decision with far-reaching environmental impacts.

2. FDA Failed to Evaluate Cumulative Impacts.

NEPA requires agencies to assess whether their proposed actions, even if individually minor, might have a cumulative impact. *Kern*, 284 F.3d at 1075. Cumulative impacts result from "past, present and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions." 40 C.F.R. § 1508.7. The cumulative impact analysis must also include an assessment of potential aesthetic, historic, cultural, economic, social, and health impacts. 40 C.F.R. § 1508.8; *Wyoming v. U.S. Dep't of Agric.*, 661 F.3d 1209, 1251 (10th Cir. 2011). A cumulative impacts analysis is especially important in the EA context, because there is a much higher risk of cumulative impacts from the many smaller decisions for which EAs are meant to be prepared. *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 895-96 (9th Cir. 2002); *Kern*, 284 F.3d. at 1076, 1078. Such an analysis must include some quantified or detailed information, not mere conclusory statements, and be timely, not deferred until future date. *Muckleshoot Indian Tribe v. U.S. Forest Serv.*, 177 F.3d 800, 810 (9th Cir. 1999); *Soda Mountain Wilderness Council v. Norton*, 424 F. Supp. 2d 1241, 1266 (E.D. Cal. 2006).

Here, FDA skipped the cumulative impacts analysis altogether. Because there were no other pending GE fish applications, FDA decided there were no "past, present, or reasonably foreseeable future actions" to consider. FDA-0022332. First, that was the wrong inquiry: the question is whether, adding this proposed approval to all other actions affecting *the environment*, specifically wild salmon, might cause a cumulative impact, including to those that rely on salmon for aesthetic, cultural, and economic reasons. The lack of any other pending GE salmon applications did not relieve FDA of its duty to examine whether it was adding another stressor to an already degraded ecosystem, and endangered salmon populations. Rather, the regulations specifically command agencies to look at other past, present, and foreseeable actions by *any agency* and *any private party*, to determine whether the proposed action might compound the existing and

future environmental degradation. *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 971-72 (9th Cir. 2006) (EA must provide a quantified assessment of project's environmental impacts when combined with other projects). Over twenty years ago, CEQ provided guidance to agencies on how to identify future actions, including how to investigate not just the plans of the proponent, but other agencies and private parties in the area.[13] FDA made no attempt to do this and its narrow focus on only other pending GE fish applications is plain error.

Second, even if the cumulative impacts analysis were limited to other GE salmon approvals, as FDA believes, its assertion that there were no "reasonably foreseeable" future actions is disingenuous; AquaBounty's plans for expansion were known from the start. *Supra*. FDA should have considered the impact of GE salmon in combination with AquaBounty's reasonably foreseeable expansion plans and other actions that affect the marine and freshwater environments impacted by FDA's decision (including socioeconomic impacts to those that rely on healthy ocean ecosystems and wild salmon). F1-00213348-51. Failing to consider all "reasonably foreseeable" actions in a cumulative impacts assessment is arbitrary and capricious. *City of Burien v. Elwell*, 2019 WL 6358039, at *1 (9th Cir. Nov. 27, 2019) (FAA failed to account for foreseeable future actions at airport); *Ctr. for Food Safety v. U.S. Army Corps of Eng'rs*, 2019 WL 5103309, at *6 (W.D. Wash. Oct. 10, 2019) (Corps failed to adequately analyze cumulative impacts from shellfish aquaculture permits on top of existing degradation, ignoring pesticide and plastic impacts).

3. FDA Failed to Consider a Reasonable Range of Alternatives

Finally, FDA violated the "heart" of the NEPA process, the consideration of alternatives to the proposed action. 40 C.F.R. § 1502.14. EAs must assess a "no action" alternative, *i.e.*, the status quo, and a reasonable range of alternatives to the proposed action. *Earth Island Inst. v. U.S. Forest Serv.*, 697 F.3d 1010, 1022 (9th Cir. 2012); *W. Watersheds Project v. Abbey*, 719 F.3d 1035, 1053 (9th Cir. 2013) (holding EA on grazing inadequate for lack of reasonable range of alternatives); 42 U.S.C. § 4332(2)(E); 40 C.F.R. § 1508.9(b). The range of "reasonable" alternatives is determined

[13] Council on Envtl. Quality, *Considering Cumulative Effects Under the National Environmental Policy Act*, 4, 19 (Jan. 1997), https://www.energy.gov/sites/prod/files/nepapub/nepa_documents/RedDont/G-CEQ-ConsidCumulEffects.pdf.

by the purpose and need for the action, which cannot be so narrow as to only allow one alternative to accomplish the goals, and must match the underlying statutory goals. *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1070 (9th Cir. 2010). While the agency need not discuss infeasible alternatives in depth, or those which do not meet the goals, it should consider more environmentally-benign alternatives, and the "existence of a viable but unexamined alternative renders an [EA] inadequate." *W. Watersheds*, 719 F.3d at 1050. Further, if the "no action" alternative is not "reasonable"—does not advance the stated goals—then discussion of merely the preferred alternative and "no action" alternative does not meet the NEPA's bare requirement for a brief discussion of reasonable alternatives. *Klamath Siskiyou Wildlands Ctr. v. Bureau of Land Mgmt.*, 2019 WL 1553673, at *4 (D. Or. Feb. 20, 2019), *report and recommendation adopted*, 2019 WL 2774317 (D. Or. July 2, 2019).

Here, FDA considered only the preferred alternative of granting AquaBounty's application and gave conclusory consideration to the "no action" alternative. FDA-22515, FDA-22352-54. FDA again cabined its own review with a strained purpose and need, stating both that its purpose was limited to approving the AquaBounty application, and that the purpose was broadly to address increasing demand for seafood and overfishing of wild stocks. FDA-022333-36. FDA has either erroneously defined its purpose and need, or failed to consider an adequate range of alternatives for its stated justifications, or both.

Ensuring an increased fish supply is a questionable purpose given the goals and purpose of the FFDCA. But assuming that is a proper purpose, there are many potential alternatives to achieve this goal that are not approval of GE salmon. F1-00213354-55 (commenters: restoration of wild Atlantic salmon populations and policies to increase sustainable commercial fishing, and non-GE methods for breeding faster growing fish). And if the purpose is limited to approving this specific GE salmon, there were still many unanalyzed alternatives, as commenters stated, including: 1) additional regulatory conditions on the approval to protect sensitive marine and freshwater areas, including temporal, process, facilities, and transport restrictions; 2) limiting the volume of GE fish grown; 3) imposing more stringent monitoring or reporting requirements; 4) requiring additional worker training; 5) refusing to permit facilities beyond FDA's jurisdiction; or 6)

granting only a limited pilot project. *E.g.,* FDA-019844-47; F1-00213354-55; F1-00008613. FDA ignored these, and explicitly rejected consideration of land-based recirculating systems despite acknowledging that they are feasible and would be "highly effective in insuring adequate physical containment of fish under commercial rearing conditions." FDA-22354-55. FDA's failure to consider any of these alternatives, including more environmentally benign ones, rendered the EA unlawful. *W. Watersheds*, 719 F.3d at 1050.

II. FDA VIOLATED THE ENDANGERED SPECIES ACT.

The ESA prohibits any federal action that "may affect" listed species unless the federal agency insures, through completion of the consultation process, that the action is not likely to jeopardize the continued existence of threatened or endangered species. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14, 402.13. FDA refused to undergo Section 7 consultation because it arbitrarily concluded its decision could have absolutely "no effect" on endangered salmon or their critical habitat. FDA's determination violated Section 7 because FDA: failed to apply the lawful "may affect" standard, narrowly defined its action and the action area, and failed to comply with the ESA's mandate to use the best available science. The agency did not evaluate (and hence underestimated) the risk and consequences of escape, and did not look beyond the effects of AquaBounty's initial application, despite widespread acknowledgement that the company planned to significantly expand.

A. The "May Effect" Standard Triggering Consultation Is a Low Bar.

Section 7's consultation process is the "heart" of the ESA. *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009). This Court previously outlined the steps in the consultation process, ECF 66 at 1-2, beginning with the requirement that an action agency consult with the expert agencies for any action that "may affect" listed species. 50 C.F.R. §§ 402.14(a), 402.01(b). The "may affect" threshold for triggering this precautionary regulatory scheme is an extremely low bar: "[A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc) (emphasis added); *id.* (consultation triggered by "*[a]ny possible effect*, whether beneficial,

benign, adverse or of an undetermined character.") (emphasis added and quotations omitted). The low threshold reflects the ESA's overall "institutionalized caution" mandate, ensuring that all federal actions that could have any effect on species on the brink of extinction are scrutinized by the expert wildlife agencies. *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015). And it "reflects Congress's awareness that expert agencies … are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species." *City of Tacoma v. F.E.R.C.*, 460 F.3d 53, 75 (D.C. Cir. 2006).

B. FDA's "No Effect" Determination Is Contrary to the Record and Violates the ESA's "May Affect" Legal Standard.

FDA concluded that its approval of GE salmon production at the PEI facility on the Atlantic coast would have no effect on endangered Atlantic salmon based on a misapplication of the legal standard and its cursory analysis of the risks posed by GE salmon. Throughout the FDA process, the Services' biologists and outside scientists expressed numerous, deep concerns that the risks from GE salmon easily surpass the very low "may affect" threshold. They emphasized that FDA should not confuse a "low" likelihood of escape with an absence of risk, and continually underscored the need for a comprehensive analysis examining both the risk of escape *and* the harms to critically endangered wild Atlantic salmon should that occur. *See supra* pp.2-6, 8-10, 11-14. For example, commenting to FDA, FWS's Northeast Region summarized that:

> Transgenic fish, regardless of where they are, *pose a clear and present danger to wild fish populations*. Given the extremely low populations of wild Atlantic salmon in the Maine DPS, any interaction between wild and transgenic salmon must be considered a *serious threat* …. The scientific literature is full of actions indicating that interactions of wild fish and aquaculture escapees (read transgenic escapees) may lead to decreased numbers of wild fish and in the worst scenario, lead to *extirpation* of the remaining stocks in the U.S.

Ex. 12 at 4 (emphases added). These staff underscored that "[i]f the brood stock from the PEI facility were released either accidentally or with malicious intent, we do not feel enough evidence has been provided to conclude the risks to natural populations of Atlantic salmon in Canada and the U.S. are negligible." *Id.* They highlighted that if there were "an escape event, competition from the GMO salmon *would negatively impact the wild stocks*. Research has shown that aquaculture-raised salmon can outcompete wild salmon, and given the already endangered status of the wild stocks,

any additional threat is amplified in their [sic] impacts." *Id.* at 5. (emphasis added). FWS geneticists echoed these same concerns and the need for more thorough analyses. FDA- 015796 ("*Any interaction between wild and transgenic salmon must be considered a serious threat*" and that "the biological containment at either the PEI or Panama facilities along with the possible interaction of AquAdvantage salmon with endangered wild salmon stocks is of *great concern*.") (emphases added); *see also* Ex. 35.

NMFS's biologists similarly recognized that "[a]n introduction of genetically engineered Atlantic salmon could pose catastrophic threats to wild listed species," and noted specifically that "[t]he egg production facility [on PEI] *may pose* a threat to … Gulf of Maine DPS Atlantic salmon." FDA-029453 (emphasis added). NMFS noted that it is possible that GE salmon will escape from the PEI facility and when they do, "they will likely [] reproduce in the wild because hatchery released fish and hatchery sterilized fish continue to behave similar to wild fish." These concerns did not abate as FDA's approval process unfolded. *See* Ex. 18 at 1 (letter to FDA highlighting NMFS's concerns about "how fertile, genetically modified, adult males are maintained on Prince Edward Island and what measures are in place to prevent those fertile and genetically modified fish from escaping and ultimately reproducing"); Ex. 20 (April 13, 2011 email) ("[W]e would have preferred if the EA analyzed a worse (sic) case scenario. There is . . . no analysis on what would happen if some [GE salmon] do escape, survive, and maybe reproduce."); Ex. 26; Ex. 32; Ex. 34.

These statements about the "clear and present danger" posed by GE salmon—and even the agency's more conservative statements about "possible" effects that "may" occur—are precisely the kind of findings that easily cross the very low "may affect" threshold to trigger consultation. In *Karuk Tribe*, the plaintiff challenged the Forest Service's failure to consult before issuing notices to conduct mining activities in ESA-protected salmon critical habitat. The Ninth Circuit rejected the intervenor miners' argument that the agency's procedural consultation duty was dependent on proof of harm. *Karuk Tribe*, 681 F.3d at 1027-29. Rather, the Court sitting en banc considered a record containing very similar agency admissions of potential risk to endangered salmon and held that this "ample evidence" alone was sufficient, as a "textual matter," to cross the "may affect" threshold and ordered consultation; *id.* at 1027 ("If the phrase 'might cause' disturbance of

fisheries habitat is given an ordinary meaning, it follows almost automatically that mining pursuant to the approv[als]… 'may affect' critical habitat of the coho salmon."). *Compare* Ex. 27 (NMFS official noting that FWS's eventual support for FDA's no effect determination was problematic because it "uses language like 'not likely' and 'insignificant,' which is generally reserved for a concurrence letter and furthermore likely indicates this action may effect listed species."). In short, the mere potential for an activity to have "any chance" of causing "any possible effect" to an endangered species is all the law requires to trigger the scrutiny of the Service's expert fish biologists through the consultation process. *Karuk Tribe*, 681 F.3d at 1027. FDA, however, unlawfully ignored the documented concerns of the Services' biologists about both the non-zero risk of release from the PEI facility, and the catastrophic consequences to endangered wild salmon to arbitrarily conclude that its GE salmon approval would have "no effect" on endangered Atlantic salmon.

C. FDA's Justifications Do Not Hold Water.

FDA's assertion that the mitigation measures obviated the need to consult is wrong on both the law and the facts. The record is replete with evidence that escapes from PEI may be unlikely, but were not impossible. *See supra* pp.4, 8-10. As scientists from agencies (unlike FDA) with actual expertise in fisheries issues as well as outside scientists emphasized, FDA was required to assess both the likelihood of the escape and the effects caused by that event. *Id.* Yet FDA failed to take the second half of that risk inquiry, in data or analysis, instead hinging completely on its hope that accidental releases simply would not occur to determine that GE salmon would have "no effect" on endangered salmon. *See supra* pp.8-10. This kind of unexamined confidence is exactly what the ESA consultation process is designed to avoid.

Contrary to FDA's blind faith in containment measures to prevent any risk of harm, FWS emphasized that even with containment systems in place, "*there is still risk of escapement* and we think this risk is *most prevalent* at the PEI facility." Ex. 12 at 4 (emphases added). FWS emphasized the need to assume that "*escape will still occur*, and protocols must be in place to deal with such a non-native organism released into the environment, and its subsequent effect on native species." *Id.* (emphasis added). *See also* FDA-2011CP-019–020 (FWS geneticist: FDA's analysis "falls short of

providing an actual risk assessment of putative environmental damages in the event of escapement" and that the "environmental analysis should provide an overview of the general risks associated with escapement or hybridization of GE and wild type individuals" and underscoring the need to understand the "degree of harm[] posed by GE organisms even when the risk of escapement is low."); Ex. 18 (highlighting NMFS's concerns about the lack of information about containment of the fertile male broodstock at PEI facility).[14]

Finally, FDA's recognition that approval would require mitigation conditions to reduce risks legally "cuts against, rather than in favor of" FDA's no effect finding. *Karuk Tribe*, 681 F.3d at 1028. As in *Karuk Tribe*, FDA's emphasis on the PEI containment measures underscores that effects are *possible*, which is all that is required to compel consultation. *Id.*

D. FDA Violated the ESA's Best Available Science Mandate.

Section 7 also requires that all agencies use the "best scientific and commercial data available" in their determinations. 16 U.S.C. § 1536(a)(2). That mandate "prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on." *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006). That is exactly what FDA did here. Faced with sharp critiques from expert scientists and concerns from the Services, FDA failed to provide any explanation for how its assessment passed muster under these standards. *See supra* pp.8-10, 11-15; *e.g.*, F1-00167784 (FDA "ignore[d] major advances" for "assessing risks from transgenic fish."). FDA relied on outdated sources, ignoring better, newer sources of information about risk. It failed to apply well-established risk assessment steps,

[14] FWS's eventual "concurrence" does not in any way inoculate FDA. First, FWS's statements have no legal significance in the ESA consultation process. As NMFS highlighted, there is no provision in the ESA consultation process for a "concurrence" in an action agency's "no effect" conclusions. Ex. 27. Rather, a no effect decision by its very nature is a unilateral action agency decision that the agency has declined to undergo expert agency consultation; there is nothing in which to concur. And indeed, as NMFS warned, such statements could be seen as drawing FWS into controversy over FDA's unilateral determinations. *Id.* (emphasizing NMFS's concern about the precedent of concurring with FDA's "no effect" determination: that every action agency would then want NMFS to for their "no effect" determinations to help them in "potential lawsuits."). Second, FWS's letter does not discuss any of the agency's previous extensive findings and comments about risk. *See, e.g.*, Ex. 28. Finally, FWS's finding was premised on a misunderstanding of the scope and nature of FDA's actions: FWS focused its determination primarily on the effects of importing processed salmon fillets (carcasses), not on the recognized threats from broodstock and fertilized egg production in the PEI facility. Ex. 5; Ex. 11 at 10 (same); Ex. 32; Ex. 33; Ex. 34.

including a failure mode analysis for the containments measures it relies on, and produce the data that it would require. *Id.*

E. FDA Unlawfully Restricted its Analysis of the Action and Action Area.

Like its NEPA analysis, FDA's no effect conclusion considered only the initial PEI and (now defunct) Panama facilities, and ignored AquaBounty's ongoing efforts to expand its operations. First, its crabbed definition of the "action" fatally undermines FDA's no effect determination. Unlike FDA, courts "interpret the term 'agency action' broadly," because "[c]aution can only be exercised if the agency takes a look at all the possible ramifications of the agency action." *Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988); *Karuk Tribe*, 681 F.3d at 1020. Agencies must also consider a broad range of "effects" of that action, including the direct effects, but also the "indirect effects" that are caused by the proposed action but occur later in time, and "interrelated actions" that are part of a larger action and lack independent utility. *Wild Fish Conservancy. v. Salazar*, 628 F.3d 513, 525 (9th Cir. 2010) (quoting 50 C.F.R. § 402.02).

FDA's attempt to limit its consideration of the action and its effects to only PEI and Panama unlawfully ignored other reasonably foreseeable indirect impacts of its GE salmon approval. AquaBounty was already submitting petitions to grow these transgenic salmon elsewhere. Ex. 7 at 2 ("As recently as February 2013, and in contradiction to the 2005 FDA application, ABT publicly stated that the company intends to import AquAdvantage® Salmon eggs into the United States"); Ex. 5 at 2; Ex. 31 at 1 (FWS official confirming three import applications and noting that "FDA was informed and quarried on all importation requests from Aquabounty.... [and that FWS] had informal discussions with both the FDA and Aquabounty on these requests."); Ex. 13; Ex. 8; Ex. 10; Ex. 14 (correspondence about West Virginia fish farm seeking to import GE eggs); Ex. 25; Ex. 26; Ex. 29. Many of the biologists and other Services' officials recognized the "action" for this consultation extended far beyond just the initial proposal. Ex. 12 at 1 (FWS: "recent statements by [AquaBounty] indicated if their application was approved they intend to sell eyed-eggs to additional confined grow-out operations in other locations."). Indeed, AquaBounty's own contemporaneous public statements admitted that they planned "'to expand capacity for the production of eggs . . . as soon as approval is granted,' and conduct commercial trials for egg sales

in multiple countries . . . ." Ex. 15 at 5-6 (comments from Trout Unlimited urging Section 7 consultation based on risks with initial proposal and company's own statements about expansion). *See also id.* at 1 (FWS Chief of Consultation Division stating that "[t]o the extent they have captured things accurately, TU makes a pretty strong case that consultation should be occurring.").

And, of course, further expansion is exactly what has happened. AquaBounty's application was, as one FWS official warned, "a foot in the door," FDA-016576; AquaBounty's subsequent expansions and supplemental NADAs are dependent on this initial approval.[15] FDA's attempt to ignore this and limit the scope of the action and effects it considered violates the ESA. *Ecological Rights Found. v. Fed. Emergency Mgmt. Agency*, 384 F. Supp. 3d 1111, 1120 (N.D. Cal. 2019) ("no effect" determination arbitrary and capricious because it "carved out" effects of related flood plain development enabled by floodplain insurance); *Nat'l Wildlife Fed'n v. Fed. Emergency Mgmt Agency*, 345 F. Supp. 2d 1151, 1175 (W.D. Wash. 2004) (similar).

Second, when evaluating whether its action "may affect" any listed species or critical habitat, FDA must examine all effects within the "action area." 50 C.F.R. §§ 402.02, 402.12; *Native Ecosystems Council*, 304 F.3d at 901. "Action area" is broadly defined to be "all areas to be affected directly or indirectly by the Federal action and *not merely the immediate area* involved in the action." 50 C.F.R. § 402.02(d) (emphasis added). The action area lies within listed Atlantic salmon habitat and its migratory path from rivers in Maine north and east along the Canadian coast, including past PEI, en route to feed and grow in the waters off of Greenland. *See* FDA-014582; FDA-014581; Ex. 18 at 1-2 (NMFS highlighting that "rearing fertile adult males" at PEI facility "potentially increase[d] the size of the action area to include the United States."); Ex. 16 at 1; FDA-022401-402 (recognizing PEI is within range of Atlantic salmon).[16] FDA offers conclusory statements, but no rational counter evidence, to support its claim that the Prince Edward Island facility is somehow "outside" the range of these salmon. *See* FDA- 022441 (assuming that waters

[15] FDA cannot rely on a potential to consult later to addresses these fatal flaws in its "no effect" conclusion. *Wild Fish Conservancy*, 628 F.3d at 524 (intent to consult later does not cure failure to complete consultation at the outset concerning action's full extent).
[16] NOAA, Salmon Migration Route Map, https://bit.ly/2OoPxhs (NMFS Map showing migratory path).

surrounding PEI facility are hostile because they do not currently contain healthy population of Atlantic salmon). For all these reasons, FDA violated the ESA.

III. FDA FAILED TO ENSURE ENVIRONMENTAL SAFETY.

Finally, FDA did not ensure GE salmon is environmentally safe, in violation of the FFDCA and the APA. 21 U.S.C. §§ 360b(a)(1), (b)(1)(H), (d)(1)-(2), (i); 21 C.F.R. §§ 514.1(b)(8), 514.105. The FFDCA instructs FDA to consider all "relevant factors" when evaluating the safety of new animal drugs. 21 U.S.C. § 360b(d)(2); ECF 229 at 20. While the statute does not provide a specific standard to demonstrate safety, Plaintiffs' prior briefing explained how the FFDCA's safety language is broad enough to encompass environmental impacts, and that environmental risk was actually a highly relevant factor in FDA's review. ECF 198 at 12-21; ECF 225 at 5-12. Despite this plain text and the record evidence belying its post hoc argument, FDA insists that it did *not* evaluate environmental risk under the FFDCA, and presents a narrow interpretation of the term "safe" as limited to the GE salmon itself and the humans who eat it. ECF 229 at 19-20. FDA has not defended the substance of its decision or presented reasons why its decision to approve GE salmon was environmentally sound. Rather, it has posited any consideration of the environmental impacts of GE salmon need only occur in its NEPA process. *Id.*

This Court previously considered whether the FFDCA's requirement to ensure the safety of a new animal drug like GE salmon includes environmental factors. *See* ECF 229. The Court agreed with Plaintiffs that "FDA considered environmental risk, at least to some degree, when it approved the conditions of use for the genetic engineering of the AquAdvantage salmon." *Id.* at 22. The Court also noted that the "term 'safe' is certainly capacious enough to reach environmental risks, and Congress carved out space 'for other relevant factors.'" *Id.* at 21. In addition, an overly narrow interpretation of the term "safe" "raises practical concerns," because it could "prohibit or severely restrict the FDA's ability to impose conditions of use, including the prohibition on growing AquAdvantage salmon in ocean net pens." *Id.* at 21-22. However, the Court did not resolve the question of whether FDA's safety evaluation was adequate and requested additional briefing on two issues: (1) the scope of judicial review for environmental factors under the FFDCA; and (2) whether "NEPA itself permits the FDA to condition approval of a new drug

on mitigation of environmental risk." *Id.* at 21-22. Both support the conclusion that environmental considerations are a relevant part of "safety" for GE salmon.

A. The Agency's Safety Determination was Arbitrary Because FDA Did Not Consider the Environmental Impacts of Escape.

FDA's approval was arbitrary because FDA did not ensure that GE salmon was environmentally "safe" for its intended use. FDA believed that "the primary risk issue [for GE salmon] . . . is environmental," F1-00183309 (ECF 215-5, Tab 41), yet still ignored or inadequately addressed important factors relevant to environmental risk, including the magnitude of impacts that would occur should GE salmon escape the PEI facility. Nor did FDA provide a rational explanation for its approval of GE salmon despite these environmental risks.

While the FFDCA does not itself provide specific "benchmarks" for FDA's "safety" review, like a maximum tolerance level for environmental risk, *see* ECF 229 at 20-21, this Court can still review FFDCA's environmental safety determination under the standard judicial review provisions of the APA. *State Farm*, 463 U.S. at 47; *Rancher's Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA*, 415 F.3d 1078, 1093-96 (9th Cir. 2005) (evaluating USDA's determination that allowing importation of Canadian cattle carried a "low" risk of mad cow disease using the APA because neither the underlying statute nor the agency defined benchmarks or standards for evaluating risk); *Am. Cyanamid Co. v. Young*, 770 F.2d 1213, 1214, 1220 (D.C. Cir. 1985) (using APA arbitrary and capricious standard to determine whether FDA's conclusions about safety and effectiveness of a new animal drug was supported by substantial evidence). Applying the APA's requirements that FDA consider relevant factors and rationally explain its decisions does not provide a "sweeping" interpretation that could give FDA an unconstitutionally broad "delegation of legislative power," nor does it mean that FDA must determine a drug that presents *any* environmental risk is "unsafe." ECF 229 at 21 (citing *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 645-46 (1980) (plurality opinion)). Even though the FFDCA does not require FDA to eliminate risk altogether, its conclusions about the acceptable level of environmental risk to approve GE salmon as "safe" must be based all relevant factors, rationally explained, and supported by clearly identified evidence in the record, as required by the APA.

Applying the APA standard of review, FDA's determination that GE salmon was "safe" was arbitrary because the agency ignored important factors related to environmental risk and did not provide "a rational connection between the facts found and the choices made." *State Farm*, 463 U.S. at 43. For example, FDA's approval of GE salmon focused entirely on the risk of release. *See supra* pp.3-5. Although FDA imposed some conditions it hoped would reduce that risk, it failed to analyze the magnitude of impact that would occur once broodstock or eggs enter the natural environment, and did not address how those conditions were sufficient to prevent the significant environmental harms that would result. *Id.* Rather, FDA ignored any effects that might result and simply assumed zero environmental risk without demonstrating that containment would effectively keep risk to a zero level. *Id.* As many scientists detailed to FDA, a proper environmental risk assessment must include an evaluation of both the risk of exposure (escape) and a full understanding of the harm from that exposure. *See supra* p.3. FDA's wholesale failure to rationally explain how—after identifying environmental risk as a critical factor to its safety determination for GE salmon—it ensured that the approval met *any* criteria or standards for environmental safety is quintessentially arbitrary. *Consol. Salmonid Cases*, 713 F. Supp. 2d 1116, 1165 (E.D. Cal. 2010) (holding that a "quintessential example of arbitrary action" is when an agency fails to provide any explanation for its decision). Further, even within its myopic focus, FDA failed to consistently identify or define, either quantitatively or qualitatively, what level of risk GE salmon posed or what level of risk it was willing to accept. *Compare* FDA-022414 ("low") *with* FDA-022419 ("highly unlikely"), FDA-022410 ("extremely low"), FDA-022433 ("within an acceptable range"). The Court cannot defer to inconsistent conclusions or those the agency itself could not articulate. *P. Coast Fedn. of Fishermen's Ass'n v. U.S. Bureau of Reclamation*, 426 F.3d 1082, 1091 (9th Cir. 2005) (Courts cannot defer to an agency's unexplained reasoning or "implicit" conclusions).

B. NEPA Does Not Provide FDA Substantive Environmental Authority to Mitigate Environmental Risk.

This Court has already determined that FDA at least attempted to address environmental risk "when it approved the conditions of use" for GE salmon. ECF 229 at 22. The only question that remains is which statute provided FDA "authority to mitigate the environmental

consequences of its approval decisions:" the FFDCA or NEPA. *Id.* Contrary to FDA's assertions, NEPA cannot give the agency substantive authority to mitigate environmental risk as a condition of approval. ECF 229 at 22 (citing *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 351 (1989)). And FDA has not identified any other potential source of authority beyond the FFDCA.

As detailed in prior briefing, the procedural requirements of NEPA simply cannot act as an independent source of authority to mitigate environmental risk. ECF 225 at 11-12; ECF 198 at 19-21 (citing cases). NEPA is a procedural statute; it does not convey independent authority to condition approvals of new animal drugs. *Robertson*, 490 U.S. at 353. "NEPA itself does not mandate particular results." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 23 (2008). It is intended to illuminate ways for the agency to "make decisions based on environmental factors not *expressly* identified in the agency's underlying statute," "NEPA does not expand an agency's substantive powers." *Nat. Res. Def. Council v. EPA*, 859 F.2d 156, 169 (D.C. Cir. 1988) (emphasis added) ("Any action taken by a federal agency must fall within the agency's appropriate province under its organic statute(s)."). FDA cannot "under the guise of carrying out its responsibilities under NEPA transmogrify" its statutory obligations. *Id.* at 170. "To do so would unjustifiably expand the agency's authority beyond its proper perimeters." *Id.*

Because the authority to take protective action must come from the underlying statute (the FFDCA), it follows that if the FFDCA does not provide such authority, FDA's attempts to restrict the approval of GE salmon in order to reduce environmental harm are toothless, a result with massive practical ramifications effects here. ECF 229 at 21-22. Namely, if FDA has no substantive authority to impose environmental safety conditions, nothing prohibits AquaBounty or any other applicant from rejecting such protective conditions, and the agency's NEPA review represents nothing more than a meaningless paperwork façade. ECF 225 at 12. That *cannot* be correct.

Moreover, the mere existence of FDA's NEPA analysis demonstrates that it must have discretion and authority to impose substantive restrictions, not that NEPA is a source of that authority. FDA's own regulations state that NEPA review is critical to ensure FDA implements necessary mitigating measures. ECF 229 at 21 (citing 21 C.F.R. §§ 25.40(e); 514.1(b)(14)). Of course, that regulation necessarily presumes FDA has the authority to impose those measures. In

analogous circumstances, the D.C. Circuit determined that NEPA can support the construction of an ambiguous statute in a way that preserves agency authority to impose environmental conditions. *Vill. of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 665-66 (D.C. Cir. 2011). In *Village of Barrington*, the agency argued that its interpretation of a statute to provide discretion to impose environmental conditions was reasonable because NEPA counseled in favor of such an interpretation. *Id.* at 665. Here, the opposite circumstances exist, but the legal outcome is the same. Although FDA could use NEPA to support a proper interpretation of the FFDCA providing it discretion to impose environmental conditions, it cannot use NEPA to support an overly narrow interpretation that *restricts* such discretion. *Id.* ("[A]n agency may appropriately decide that NEPA counsels in favor of the more environmentally protective interpretation so long as that interpretation 'fall[s] within the agency's appropriate province under its organic statute(s).'" (quoting *Nat. Res. Def. Council*, 859 F.2d at 169). The agency's NEPA analysis is itself evidence to support a proper reading of the FFDCA's substantive authority as including environmental safety, not a substitute or source of that substantive authority.

CONCLUSION

Accordingly, Plaintiffs request the Court grant their summary judgment motion, declare FDA's approval violated the FFDCA, NEPA, ESA, and APA, and vacate the approval. *See* 5 U.S.C. § 706(2); *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015).

Respectfully submitted,

/s/ George Kimbrell
George A. Kimbrell (*Pro Hac Vice*)
Amy van Saun (*Pro Hac Vice*)
Center for Food Safety
2009 NE Alberta Street, Suite 207
Portland, OR 97211
(971) 271-7372
Emails: gkimbrell@centerforfoodsafety.org
avansaun@centerforfoodsafety.org

/s/ Stephen D. Mashuda_____
Stephen D. Mashuda (*Pro Hac Vice*)
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
T: (206) 343-7340 / F: (206) 343-1526
Email: smashuda@earthjustice.org

Brettny Hardy (CSB # 316231)
Earthjustice
50 California St, Suite 500
San Francisco, CA 94111
T: (415) 217-2142
Email: bhardy@earthjustice.org

Counsel for Plaintiffs